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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 18 FEB 2002

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Applicant's or agent's file reference 59131-A-PCT/		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/15621	International filing date (day/month/year) 07 June 2000 (07.06.2000)	Priority date (day/month/year) 07 June 1999 (07.06.1999)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00; C01H 21/02, 21/04; C07K 14/00; C12N 5/00, 5/06, 5/10, 15/00, 15/09, 15/11, 15/12, 15/63 and US Cl.: 435/69.1, 70.1, 320.1, 325, 455; 514/2; 530/350; 536/23.1, 23.5, 24.1			
Applicant THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>18</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>18</u> sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input checked="" type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 05 January 2001 (05.01.2001)		Date of completion of this report 21 December 2001 (21.12.2001)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Authorized officer Jeanine Enewold Goldberg Telephone No. (703) 308-0196	

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/15621

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

☐

the international application as originally filed.

☒

the description:

pages none as originally filedpages none filed with the demandpages NONE filed with the letter of \_\_\_\_\_.☒

the claims:

pages NONE as originally filedpages NONE as amended (together with any statement) under Article 19pages NONE filed with the demandpages 87-104 filed with the letter of 28 September 2001 (28.09.2001)☐

the drawings:

pages NONE as originally filedpages NONE filed with the demandpages NONE filed with the letter of \_\_\_\_\_.☐

the sequence listing part of the description:

pages NONE as originally filedpages NONE filed with the demandpages NONE filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐

the language of publication of the international application (under Rule 48.3(b)).

☐

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐

contained in the international application in printed form.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority in written form.

☐

furnished subsequently to this Authority in computer readable form.

☐

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:☐the description, pages NONE☐the claims, Nos. NONE☐the drawings, sheets/fig NONE5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/15621

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 5-7,12,15,26-28,32,33,35-37,39-48 and 50-137

because:

- ☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-7,35-37 and 39 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 5-7, 35-37, 39 are dependent claims not drafted in accordance with the second and third sentences of Rule 6.5(a). These claims were inadvertently included in the Lack of Unity made in Chapter 1.

- ☒ the claims, or said claims Nos. 12,15,32,33,36,37,53 and 54 are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 26-28, 39-48, 50-52, 55-137

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☒ the written form has not been furnished or does not comply with the standard.
- ☒ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)

Claims 1-4, 8-11, 13-14, 16-25, 29-31, 34, 38, 49

YES

Claims NONE

NO

Inventive Step (IS)

Claims 1-4, 8-11, 13-14, 16-25, 29-31, 34, 38, 49

YES

Claims NONE

NO

Industrial Applicability (IA)

Claims 1-4, 8-11, 13-14, 16-25, 29-31, 34, 38, 49

YES

Claims NONE

NO

**2. CITATIONS AND EXPLANATIONS (Rule 70.7)**

Claims 1-4, 8-11, 13-14, 16-25, 29-31, 34, 38, 49 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a nucleic acid molecule encoding a p75<sup>ntr</sup>-associated cell death executor, vectors encoding the sequences, host cell containing the vector and the polypeptides made by the host cell.

----- NEW CITATIONS -----

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PTC Rule 66.2(a)(iii) in the form or contents thereof: the description contains nucleic acid and amino acid sequences which are not identified by SEQ ID NO:.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to contain an adequate written description of isolated nucleic acid sequences and amino acid sequences encoding polypeptide of a p75NTR associated cell death executor. The description is inadequate because: the description does not provide sufficient information with respect to all of the possible nucleic acid sequences and amino acid sequences embraced by the claims.

Claims 1-4, 8-11, 13-14, 16-25, 29-31, 34, 38, 49 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not adequately described in writing, as required under PCT Rule 5.1(a)(iii), for the reasons set forth in the immediately preceding paragraph.